UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

September 20, 2013

Docket Nos. 03001786
03037773

License Nos. 19-00296-10
19-00296-21

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
Department of Health & Human Services
National Institutes of Health
Building 1, Room 103
1 Center Drive, MSC0140
Bethesda, MD 20892-0140

SUBJECT: NRC INSPECTION REPORT NOS. 03001786/2013001 AND 03037773/2013001, DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, BALTIMORE, AND FREDERICK, MARYLAND AND NOTICE OF VIOLATION

Dear Dr. Gottesman:

On June 17-21, 2013, Penny Lanzisera, Robin Elliott, John Miller, and Janice Nguyen of this office conducted a safety inspection of the National Institutes of Health (NIH) facilities located at the above addresses of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated June 21, 2013, and information discussed during telephone conversations on July 2, July 9, and August 30, 2013, was also examined as part of the inspection. The preliminary findings of the inspection were discussed with Dr. Alfred Johnson, Director of the Office of Research Services, and other members of your organization at the conclusion of the on-site inspection. Inspector review of issues identified during the on-site inspection continued through August 30, 2013. The enclosed report presents the results of this inspection.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that five Severity Level 4 violations of NRC requirements occurred. Specifically: 1) on July 28, 2011 and September 4, 2012, the NIH Radiation Safety Committee (RSC) approved an authorized user and an authorized medical physicist for the use of a remote afterloader unit under 10 CFR 35.600 based on board certifications that were not approved by the Nuclear Regulatory Commission, in accordance with Condition 11.B. of License No. 19-00296-10; 2) as of July 18, 2013, an authorized user from radiation oncology, a type of use permitted by the license, was not named to the NIH RSC, in accordance with 10 CFR 35.24; 3) NIH upgraded and used a remote afterloader unit model from January 15, 2013, to the present that was not specifically listed on NRC License No. 19-00296-10; 4) an NIH researcher did not make an adequate survey of a work area on June 18, 2013, to evaluate residual

radioactivity and potential radiological hazards, in accordance with 10 CFR 20.1501(a); and 5) NIH did not monitor the external surfaces for contamination of labeled packages (DOT Yellow II) received at their Baltimore site on March 1, May 24 and May 28, 2013, in accordance with 10 CFR 20.1906(b)(1) and (c).

The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC. Also, Item A as listed in the Notice is a repeat violation that was identified during a previous inspection of your licensed program. This previous violation was documented in the Notice of Violation enclosed with our letter dated May 18, 2011. Although we had verified that you took corrective action to address the previous violation, the current violation is of concern because your preventative actions were not effective in preventing recurrence and indicate a lack of attention to detail in the review of training and experience documentation by your RSC. The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the potential for use of licensed material by unqualified individuals which could result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application.

During our preliminary inspection exit meeting on June 21, 2013, your staff indicated that NIH is committed to radiation safety and to compliance with NRC regulations and license conditions and that corrective and preventative actions were in progress for each violation identified. Further, on June 21, 2013, your staff submitted an amendment request to correctly list the remote afterloader unit model possessed and, on August 30, 2013, your RSO stated verbally that corrective and preventative actions were completed for the remaining violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, “Suggested Guidance Related to Development and Implementation of Corrective Action,” is enclosed. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC’s "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

Original Signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:
1. Inspection Report
2. Notice of Violation
3. NRC Information Notice 96-28

cc: Nancy E. Newman, Radiation Safety Officer
State of Maryland

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cc: Nancy E. Newman, Radiation Safety Officer
State of Maryland

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DATE	09/05/13		09/05/13		09/05/13		09/05/13		09/20/13

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NOTICE OF VIOLATION

National Institutes of Health
Bethesda, MD

Docket No. 03001786
License No. 19-00296-10

During an NRC inspection conducted on June 17-21, 2013, and continuing through August 30, 2013, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Condition 11.B. of License No. 19-00296-10 requires, in part, that individuals designated to work as an authorized user (AU) or an authorized medical physicist (AMP), as defined in 10 CFR 35.2, shall meet the training, experience, and recentness of training criteria established in 10 CFR Part 35 and shall be designated, in writing, by the licensee's Radiation Safety Committee (RSC).

   10 CFR 35.51(a) and 10 CFR 35.690(a) require, in part, that the AMP and AU be certified by a specialty board whose certification process has been recognized by the Commission. The names of board certifications which have been recognized by the Commission will be posted on the NRC's web page.

   Contrary to the above, on September 4, 2012, and July 28, 2011, NIH's RSC designated individuals to work as an AU and AMP, respectively, as defined in 10 CFR 35.2, and did not obtain appropriate training and experience documentation. Specifically, the NIH RSC approved the AU and the AMP for the use of a remote afterloader unit under 10 CFR 35.600 based on board certifications that were not recognized by the Commission.

   This is a Severity Level IV violation (Section 6.3)

B. 10 CFR 35.24(f) requires, in part, that the RSC established to oversee all uses of byproduct material permitted by the license include an AU of each type of use permitted by the license.

   Contrary to the above, as of June 18, 2013, the RSC established to oversee all uses of byproduct material permitted by the license did not include an AU for each type of use permitted by the license. Specifically, License No. 19-00296-10 authorized remote afterloading brachytherapy; however, an AU for this type of use was not included on the RSC.

   This is a Severity Level IV violation (Section 6.3)

C. Condition 9.L. of License No. 19-00296-10 requires that the high dose rate remote afterloader unit used be limited to the model number specifically listed.

Contrary to the above, as of January 15, 2013, the high dose rate remote afterloader unit used was not limited to the model number specifically listed in Condition 9.L. of License No. 19-00296-10. Specifically, NIH updated the model used to a new model and did not amend their NRC license.

This is a Severity Level IV violation (Section 6.3).

D. 10 CFR 20.1501(a) requires, in part, that each licensee shall make surveys of areas that may be necessary for the licensee to comply with the regulations in this part and are reasonable under the circumstances to evaluate the potential radiological hazard of the residual radioactivity detected.

Contrary to the above, on June 18, 2013, the licensee did not make a survey of an area that may be necessary for the licensee to comply with the regulations in this part and are reasonable under the circumstances to evaluate the potential radiological hazard of the residual radioactivity detected. Specifically, an NIH researcher conducted licensed activities on June 18, 2013, using 200 microcuries of phosphorus-32 in a room in Building 37 on the Bethesda Campus and the researcher conducted a survey at the end of radioactive material use; however, the survey was not adequate because it failed to detect approximately 35,000 counts per minute (109,000 disintegrations per minute) on the floor located directly below the work area.

This is a Severity Level IV violation (Section 6.7)

E. 10 CFR 20.1906(b)(1) and (c) require, in part, that each licensee monitor the external surfaces of a labeled package for contamination and perform the monitoring as soon as practical after receipt of the package but not later than 3 hours after the package is received at the licensee's facility.

Contrary to the above, on March 1, May 24, and May 28, 2013, the licensee failed to monitor the external surfaces of labeled packages for contamination and perform the monitoring as soon as practical after receipt of the package but not later than 3 hours after the package is received at the licensee's facility. Specifically, NIH did not monitor the external surfaces for contamination of labeled packages (DOT Yellow II) received on the dates listed above at their Baltimore site.

This is a Severity Level IV violation (Section 6.7)

Pursuant to the provisions of 10 CFR 2.201, National Institutes of Health is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the

violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 20th day of September 2013